

Food and Drug Administration, HHS

device is FDA's guidance document entitled "Class II Special Controls Guidance Document: In Vitro HIV Drug Resistance Genotype Assay." See §866.1(e) for the availability of this guidance document.

[72 FR 44382, Aug. 8, 2007]

§ 866.3980 Respiratory viral panel multiplex nucleic acid assay.

(a) *Identification.* A respiratory viral panel multiplex nucleic acid assay is a qualitative in vitro diagnostic device intended to simultaneously detect and identify multiple viral nucleic acids extracted from human respiratory specimens or viral culture. The detection and identification of a specific viral nucleic acid from individuals exhibiting signs and symptoms of respiratory infection aids in the diagnosis of respiratory viral infection when used in conjunction with other clinical and laboratory findings. The device is intended for detection and identification of a combination of the following viruses:

- (1) Influenza A and Influenza B;
- (2) Influenza A subtype H1 and Influenza A subtype H3;
- (3) Respiratory Syncytial Virus subtype A and Respiratory Syncytial Virus subtype B;
- (4) Parainfluenza 1, Parainfluenza 2, and Parainfluenza 3 virus;
- (5) Human Metapneumovirus;
- (6) Rhinovirus; and
- (7) Adenovirus.

(b) *Classification.* Class II (special controls). The special controls are:

(1) FDA's guidance document entitled "Class II Special Controls Guidance Document: Respiratory Viral Panel Multiplex Nucleic Acid Assay;"

(2) For a device that detects and identifies Human Metapneumovirus, FDA's guidance document entitled "Class II Special Controls Guidance Document: Testing for Human Metapneumovirus (hMPV) Using Nucleic Acid Assays;" and

(3) For a device that detects and differentiates Influenza A subtype H1 and subtype H3, FDA's guidance document entitled "Class II Special Controls Guidance Document: Testing for Detection and Differentiation of Influenza A Virus Subtypes Using Multiplex Nucleic Acid Assays." See §866.1(e) for the

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availability of these guidance documents.

[74 FR 52138, Oct. 9, 2009]

Subpart E—Immunology Laboratory Equipment and Reagents

§ 866.4070 RNA Preanalytical Systems.

(a) *Identification.* RNA Preanalytical Systems are devices intended to collect, store, and transport patient specimens, and stabilize intracellular RNA from the specimens, for subsequent isolation and purification of the intracellular RNA for RT-PCR used in in vitro molecular diagnostic testing.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: RNA Preanalytical Systems (RNA Collection, Stabilization and Purification System for RT-PCR Used in Molecular Diagnostic Testing)." See §866.1(e) for the availability of this guidance document.

[70 FR 49863, Aug. 25, 2005]

§ 866.4100 Complement reagent.

(a) *Identification.* A complement reagent is a device that consists of complement, a naturally occurring serum protein from any warm-blooded animal such as guinea pigs, that may be included as a component part of serological test kits used in the diagnosis of disease.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §866.9.

[47 FR 50823, Nov. 9, 2001, as amended at 66 FR 38792, July 25, 2001]

§ 866.4500 Immuno-electrophoresis equipment.

(a) *Identification.* Immuno-electrophoresis equipment for clinical use with its electrical power supply is a device used for separating protein molecules. Immuno-electrophoresis is a procedure in which a complex protein mixture is placed in an agar gel and the various proteins are separated on the basis of